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Sub 027

(1) A system for monitoring a sterilization or disinfection process comprising:  
a container defining a first space and a second space, the first space and second space being in fluid communication with each other;  
the first space being adapted to contain one or more articles to be sterilized or disinfected;  
the second space having therein at least one indicator for indicating at least one parameter relevant to the sterilization or disinfection process;  
an antimicrobial source for providing an antimicrobial agent to the first space; and  
wherein the second area is in fluid communication with the antimicrobial source only through the first space.

(2) A system according to claim 1 wherein the antimicrobial source comprises an aperture into the first space from outside of the container whereby antimicrobial fluids in an area around the container may diffuse into the first space through the aperture.

(3) A system according to claim 1 wherein the antimicrobial source comprises a supply of antimicrobial fluid within the first space.

(4) A system according to claim 1 wherein the container is impermeable to microorganisms.

(5) A system according to claim 1 and further comprising a flow restriction between the first space and the second space.

(6) A system according to claim 1 wherein the second space is detachable from the first space.

(7) A system according to claim 1 wherein the container comprises a pouch.

(8) A system according to claim 1 wherein the indicator comprises a biological indicator.

9. A system according to claim 1 wherein the indicator comprises a chemical indicator.

5 10. A system according to claim 9 wherein the container comprises a pouch and wherein the chemical indicator is printed on the pouch inside the second space.

10 11. A system according to claim 1 wherein the first space is divided into two or more subspaces connected in series between the source of antimicrobial fluid and the second space.

12. A system according to claim 11 wherein at least a portion of the subspaces are detachable from the container.

15 13. A system according to claim 1 wherein the antimicrobial fluid comprises hydrogen peroxide.

20 14. A system according to claim 1 and further comprising a fan adapted to assist flow through the container from the source of antimicrobial fluid to the second space.

15. A method for monitoring a disinfection or sterilization procedure comprising the steps of:

25 providing a container having a first space and a second space in fluid communication with each other;

placing an article to be disinfected or sterilized into the first area;

placing at least one indicator into the second area;

providing an antimicrobial agent to the first space; and

30 flowing said antimicrobial agent to the second area only from the first area and reading a relevant function of the disinfection or sterilization procedure with the indicator.

16. A method according to claim 15 wherein the indicator is a biological indicator and the relevant function is the overall efficacy of the disinfection or sterilization

procedure.

(17) A method according to claim 15 wherein the indicator is a chemical indicator and the relevant function is the presence of the antimicrobial agent.

(18) A method according to claim 15 wherein the antimicrobial agent comprises hydrogen peroxide.

(19) A method according to claim 18 wherein the antimicrobial agent comprises hydrogen peroxide vapor.

(20) A method according to claim 15 and further comprising the step of assisting the flow of the antimicrobial agent through the first space and to the second space with a fan.

(21) a method according to claim 15 and further comprising the step of recirculating the antimicrobial agent back to the first space from the second space.

(22) A method according to claim 15 and further comprising the step of detaching the second space from the first space.

(23) A method according to claim 15 wherein the container is a pouch and further comprising the step of sealing the first space from the second space after flowing the antimicrobial agent into the second space and then removing the indicator from the second space.

(24) A method according to claim 23 wherein the step of sealing the first space from the second space comprises heat sealing a portion of the pouch between the first space and the second space.